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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,633	06/09/2006	Todd Maibach	14PS-129581	8600

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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09/09/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,633	Applicant(s) MAIBACH, TODD	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 20-35 and 37-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and response dated 6-30-10 is acknowledged.

Claims 18-19 and 36 read on the claimed species and are examined in this action.

Claims 1-17, 20-35 and 37-104 have been withdrawn as being non-elected.

In response to the amendment, the rejection of record has been replaced with the following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6596298 to Leung et al in view of US 2007/0184093 to Hang and Chobanian et al or Hang in view of Chobanian.

Leung et al. teach edible films that preferably include pullulan, antimicrobially effective amounts of thymol, methyl salicylate, eucalyptol, menthol; and contain pharmaceutical actives (Abstract, col. 2 summary of the invention). The film more preferably comprises pullulan as a film forming agent in amounts of 45% to 70% (col. 5, L 1-10, col. 11 and examples in col. 17-18) and further Leung suggests incorporating a number of medicaments or pharmacological agents (col. 12). Leung does not teach nitroglycerin and combination of nitroglycerin with other cardiovascular agents.

Hang teaches soluble films comprising a soluble polymer and a strengthening polymer (0017) for delivery of emergency medical care active agents such as

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nitroglycerin (0019). For the soluble films, Hang preferably teaches pullulan (0030).

Hang does not teach an embodiment containing nitroglycerin and lacks the combination of nitroglycerin with other cardiovascular agents. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to incorporate nitroglycerin in the fast dissolving oral film containing pullulan of Leung or Hang because both Leung and Hang teach pullulan films for fast dissolution and for the delivery of oral active agents and Hang particularly teaches the films for nitroglycerin delivery. Further, a skilled artisan would have been able to employ combinations of medicaments for treating cardiovascular conditions with an expectation to at least achieve an additional protective effect if not a synergistic effect, as suggested by Chobanian et al (abstract, col. 3-4).

Response to Arguments

2. Applicant's arguments filed 6-30-10 have been fully considered but they are not persuasive.
3. Applicants' arguments with respect to the teachings of Keith have been rendered moot because Keith reference is no longer applied to reject the claims.
4. Applicants' arguments regarding the teaching of PEG and pullulan by Leung is moot in light of the new rejection. Applicants agree that Leung teaches fast dissolving films comprising pullulan films and therefore meet the limitations "rapid-dissolving and rapid transmucosal delivery". In this regard, Hang also teaches pullulan quick dissolution and oral delivery of nitroglycerin.

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5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
September 7, 2010